DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 5 2004

Hemedex, Inc.
c/o Ms. Debbie Iampietro
President, QRC Consulting
7 Tiffany Trail
HOPKINTON MA 01748

Re: K032127
Trade/Device Name: Hemedex Fixation Device
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Product Code: 78 KNY
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Product Code: 78 FGE
Regulation Number: 21 CFR §870.2100
Regulation Name: Cardiovascular blood flow meter
Regulatory Class: 74 DPW
Regulation Number: 21 CFR §870.2120
Regulation Name: Extravascular blood flow probe
Product Code: 74 DPT
Regulatory Class: II
Dated: October 2, 2003
Received: October 3, 2003

Dear Ms. Iampietro:

This letter corrects our substantially equivalent letter of December 30, 2003, regarding the Hemedex Fixation Device. One of the product codes was originally listed as 78 KYN, but should have been listed as 78 KNY.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

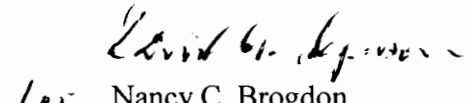
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032127

Device Name: Fixation Device

Indications For Use:

The Hemedex Fixation Device is intended to be used on the patient's skin to secure the percutaneous placement of the QFlow Perfusion Probe.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032127

K032127

510K Summary of Safety and Effectiveness

1. Sponsor Name

   Hemedex, Inc.
   222 Third Street, Suite T123
   Cambridge, MA 02142
   USA

2. Device Name

   QFlow 500 Probe Fixation Disk

3. Identification of Predicate or Legally Marketed Device

   UreSil Fixation Device (K914699)

4. Device Description

   The Hemedex Fixation Device is a compact soft silicone disk with a securing clamp and adhesive dressing for securing a probe or catheter to the patients skin. The clear pressure sensitive adhesive dressing allows for easy visual inspection of catheter entry site.

5. Intended Use

   The Hemedex Fixation Device is intended to be used on the patient's skin to secure the percutaneous placement of the QFlow Perfusion Probe

6. Comparison of Technological Characteristics

   This device is the exact same device as that marketed by UreSil under K914699 except the diameter has been reduced to accommodate the QFlow Probe OD. The materials are the same as that in K914699. In fact UreSil is the manufacturer of the Hemedex Fixation device.

7 Performance Testing

   Bench testing was conducted to demonstrate that this device meets the requirements of its intended use and meets the specified performance criteria.